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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,389	12/29/2003	Mineo Yamakawa	070702006800	8159

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EXAMINER	
WRIGHT, PATRICIA KATHRYN	
ART UNIT	PAPER NUMBER
1743	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,389	YAMAKAWA ET AL.	
	Examiner	Art Unit	
	P. Kathryn Wright	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *3-7,24-28 and 41-54* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,8-23 and 29-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. claims 1-50 drawn to a microfluidic device, classified in class 422, subclass 68.1;

   II. claims 51-54, drawn to a method of making a microfluidic device, classified in class 216.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process. Specifically, the product of group I does not require depositing polysilicon on the substrate and using low-pressure chemical vapor disposition to form the porous membrane.

3. In the event group I is elected, the following species election must be also made:

   i. Fig. 3a-e (drawn to claims 1-2, 8-23, 29-40);

   ii. microfluidic device with both field-force gradient mechanism and molecular trapping mechanism (no figure; drawn to claims 3-7, 24-28, 49-50);

   iii. Fig. 3f (drawn to claims 41-48).

4. In the event species i is elected, the following species election to the field-force/gradient mechanism in claims 2 and 23 must be also made:

   a. an electronic field;

b. magnetic field;

c. acoustic wave and ultrasound;

d. light with a specific wavelength.

5. In the event species ii is elected, the following species election to the field-force/gradient mechanism in claim 50 must be also made:

a. an electronic field;

b. magnetic field;

c. acoustic wave and ultrasound;

d. light with a specific wavelength.

6. Because these inventions are distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, and require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

7. During a telephone conversation with Raj Dave on April 30, 2007 a provisional election was made with traverse to prosecute the invention of group I, claims 1-50, species i (claims 1-2, 8-23, 29-40) and sub-species a (electronic field). Affirmation of this election must be made by applicant in replying to this Office action. Claims 41-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

9. The drawings are objected to because Fig. 11 contains an arrow with no corresponding reference no. The arrow appears to be pointing at the porous membrane 710. Clarification is required.

10. The drawings are also objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "154", solid arrows in Fig. 3d (see par. [0030]) and "208", cross-channel area in Fig. 5, (see par. [0038]).

11. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

12. The disclosure is objected to because of the following informalities: the specification makes reference to Fig. 11a in the Brief Description of the Drawings section. There is no Fig. 11a, only Fig. 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1-2, 8-10, 12, 15, 19-23, 29-31, 33 and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent Pub. no. 2006/0124459 to Strand et al. (hereinafter "Strand").

Strand teaches a microfluidic device (see par. [0113]) comprising a source fluid flow channel (Fig. 2; sample channel) and a target fluid flow channel (Fig. 2; electrolyte channel). The target fluid flow channel being in fluid communication with the source fluid flow channel at a cross-channel area, wherein a porous membrane (Fig. 2; conductive membrane) separates the source fluid flow channel from the target fluid flow channel in the cross-channel area. Note that the source fluid flow channel and target fluid flow channel are formed in substrate, see Figs. 7A-C (claim 15). Strand also teaches a field-force/gradient mechanism (electrode array 98) proximate the porous membrane which

generates an electric field. The magnitude of the field gradient may be manipulated by adjusting the voltage applied to the electrodes. The porous membrane is conductive for the passage of small ionic species therethrough (see par. [0112]), thereby acting as a sensor in the same manner as that disclosed in the instant application. Strand also teaches a light source and detector (UV-Vis spectrometer) focused at the cross-sectional area (see par. [0121]-[0122] and par. [0141]). Please note that a recitation with respect to the manner in which a claimed apparatus is intended to be employed, (i.e., disposed or reused) fails to differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claims 11, 13, 17-18, 32, 34-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Pub. no. 2006/0124459 to Strand et al., in view of US Patent No. 6,248,539 Ghardiri et al., hereinafter ("Ghardiri").

The teachings of Strand have been summarized *supra.*

Strand does not teach a microfluidic device having a single crystal or polysilicon porous membrane integrally formed on a silicon substrate. Furthermore, Strand does not explicitly set forth the thickness of the membrane.

Ghardiri teaches a microfluidic device having a porous layer or membrane integrally formed on a single crystalline, or amorphous silicon substrate. The use of the porous silicon membrane makes possible the highly sensitive detection, identification and quantification of small analyte molecules at low concentrations (see col. 3, lines 59-63 and col. 5, lines 21+). The thickness of the membrane is between the range of 0.5 to 30 microns see col. 3, lines 30+ (claims 11, 32). The system of Ghardiri also includes a light source and CCD detector in communication with data collection equipment that collects data pertaining to changes in the optical characteristic of the porous membrane.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to use the porous silicon substrate of Ghardiri in the microfluidic system of Strand since the use of the porous silicon substrate makes possible highly sensitive detection, identification and quantification of small analyte molecules (see abstract).

18. Claim 14, 16, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Pub. no. 2006/0124459 to Strand, in view of US Patent No. 6,248,539

Ghardiri, and in further view of US Patent No. 6,806,543 to Yamakawa et al., (hereinafter "Yamakawa").

The teachings of Strand and Ghardiri have been summarized above. Neither Strand nor Ghardiri explicitly states the use of a porous membrane made of porous polysilicon and a substrate made of polydimethyl siloxane (PDMS).

Yamakawa does teach a microfluidic device having a porous membrane which may be made from a wide-range of materials. Such materials include but are not limited to single crystal porous silicon (PSi), porous polysilicon (PPSi), porous silica, zeolites, photoresists, porous crystals/aggregates, etc. These types of porous membranes are well suited for molecular separation. Generally, the substrate may comprise any suitable material in which the microfluidic channels may be formed (e.g., silicon, quartz, polydimethyl siloxane (PDMS), SU-8 photoresists), including polymers such as polymethylmethacrylate (PMMA), etc. The use of polydimethyl siloxane is desirable since it is chemically inert and inexpensive.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to use the porous membrane and porous silicon substrate of Yamakawa in the combined microfluidic system of Strand and Ghardiri since the use of these types of porous membranes are well suited for molecular separation. Similarly, the use of polydimethyl siloxane is desirable since it is chemically inert and inexpensive.

Furthermore, with respect to the materials of construction, it would have been obvious to one of ordinary skill in the art to determine the optimum materials of construction based on considerations such as cost, ease of manufacture, reactions with the processing agents and/or maintaining the required reaction conditions.

Conclusion

19. No claims allowed.

20. The prior art is made of record and is considered pertinent to applicant's disclosure for teaching the state of the art are as follows: Chow (U.S. Patent no. 6,321,791, Karp et al. (US Patent Pub. No. 2003/0223913), Nelson (US Patent no. 6,344,326) and (US Patent no. 5,770,029), and Tolley et al. (U.S. Patent Pub. No. 2003/0094369), Swinehart et al., (US Patent Pub. No. 2005/0129580), Bosch et al., (US Patent Pub. no. 2005/0173315), Sundararajan et al., (US Patent Pub. 2005/0221333) and Lee et al., (US Patent Pub. No. 2004/0258571).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

May 14, 2007

pkw

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